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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,020	09/28/2000	Robert S. Matson	2014-181	7650
22471	7590	07/31/2002		
BECKMAN COULTER INC 4300 NORTH HARBOR BOULEVARD P O BOX 3100 FULLERTON, CA 928343100			EXAMINER	
			DAVIS, DEBORAH A	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 07/31/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)
	09/675,020	MATSON ET AL.
	Examiner	Art Unit
	Deborah A Davis	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 April 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-25 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

3. Page 7, line 20 and page 12, line 10 of the specification is objected to because they each contain symbols behind the terms Biomek Gripper Tool and Orca without an explanation of their meaning.

Appropriate explanation is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 1, line 1, the term "activated" is vague and indefinite as to how the areas are "activated" for immobilization of biorecognition material.
6. Claim 8, line 3, the term "one or more array formation areas" is confusing and indefinite since it is unclear whether these areas are the same ones recited in claim 1.
7. Claim 14, line 3, recite "the surface areas of" lack antecedent basis.
7. Claims 9 and 19 recites "an array formation area", it is unclear whether this array formation area is the same array formation area as recited in claim I.
8. Claim 18 is vague and indefinite because it is not clear whether the terms in parenthesis are a part of the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 9-12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Donald B. Rising (USP#5,554,536).

Donald B. Rising anticipates the instant claims by teaching a micowell membrane plate for conducting biological analysis (See abstract); the barriers between

each well can be formed of suitable materials (i.e. flexible material) such as cellulose esters, polyvinylidene fluoride and is activated for immobilization of biorecognition materials such that cells are grown on the surface of microporous membranes for several days to allow for attachment of dependent cells to form a confluent layer (col. 1, lines 61-66). The microwell plate has a plurality of wells and each well has an array formation (See Figure 1). Barriers such as capillary gaps can be between 0.01 mm and 1.0mm (col. 4, lines 25-29). The microwell plate device has a rectangular tray made of suitable material such as glycol modified polyethylene terephthalate (i.e. flexible material) and there are peripheral depressions between each well formation (See Figure 1 and col. 3, lines 40-59). The microwell plate is used for cell culture, for studying in vitro living cells, and assays for analyzing cell function (col 3, lines 33-37) and has improved contamination prevention features (See abstract. 1-2). Biological reagents are added to each individual well (col. 1, lines 22-31). This invention also relates to multiwelled plates for evaluating assays (col. 1, lines 7-13).

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-5 and 9-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Coassin et al (USP# 6,232,114).

Coassin et al teaches multi-well plates that are used for fluorescence measurements of biological samples (See title). Uses for multi-well plates are well known in the art, which include diagnostic assays, chemical or biochemical binding assays, filtrations assays and chemical synthesis. The multi-well plates are made of polymeric materials (col. 7, lines 59-66) and are activated for immobilization of biorecognition materials such that covalent or non-covalent attachment sites on the material can be used to attach moieties such as assay components (col. 9, lines 10-15). The multi-well plates can be manufactured in a variety of ways shapes and sizes. The instant invention contains multi-well plate with an array of wells that contain barriers between the wells to prevent fluid flow and the visible height is less than 4mm (See Figure 1A). There are peripheral depressions between the wells of the plate (See abstract). Commonly used well plates can include 1536 to 9600 wells in one plate (col. 7, lines 40-42). The reaction areas on the multi-well plates such as the polymers in the plate can be activated to be covalent or non-covalent to aid the attaching of chemical moieties (col. 9, lines 9-14). Various labels may be used in the assays using the present invention (col. 18, line 25-26). Multi-well plates can be coated by known methods such as printing, spraying, radiant energy and other known methods in the art (col. 9, lines 1-

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- 5). Manufacturing methods can include a variety of processes such as injection molding, heat welding etc. (col. 15, lines 15-20).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donald B. Rising or Coasssin et al in view of Ashok R. Sanadi (USP#5,516,490).

The teachings of Donald B Rising or Coasssin et al are set forth above and differ from the instant claim by not teaching a gasket defining a plurality of holes being disposed over the substrate.

However, Ashok R. Sanadi teaches a gasket being disposed over the substrate and sealed thereto and each area of the substrate is exposed by a hole of the gasket (col. 3, lines 34-38) in order to prevent cross-contamination of samples in the wells (col. 6, lines 34-48).

It would have been obvious to one of ordinary skill in the art to incorporate the gasket of Ashok R. Sanadi into the microplate assemblies of Donald B. Rising or Coasssin et al to prevent cross contamination by providing a seal between the individual wells.

5. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donald B. Rising or Coassin et al in view of Patrick Gaillard (USP# 5,948,363).

The teachings of Donald B. Rising or Coassin et al are set forth above and differ from the instant claims in not teaching the detachable rigid frame with the well strips. However, Patrick Gaillard teaches a rigid frame that is detachable from the well strips (See abstract). The frame comprises spaced apart raised elements (i.e. rigid hangers) for aligning the well strips (col. 3, lines 31-39).

It would have been obvious to one of ordinary skill in the art to incorporate the detachable rigid frame with the well strips in the microplate of Donald B. Rising or Coassin et al for the purpose of aligning the well strips in place. Furthermore, It is also a well known practice in the art to include micro-well strips sized and configured so as to provide exactly 96 wells in a frame (col. 3, lines 13-18).

6. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donald B. Rising or Coassin et al in view of Mathus et al (USP#5,858,309).

The teachings of Donald B. Rising and Coassin et al are set forth above and differ from the instant claims in not pointing out the material thickness in the microplate and flexural modulus; hardness and specific temperature as recited in claim 18.

However, Mathus et al teaches microplates and methods for manufacturing microplates. This microplate is designed to allow UV radiation to pass through the bottom of the wells (See abstract). In the detailed description of the invention, a

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microplate with a material thickness of 7.5mils is used to obtain the desired wavelength (col. 4, lines 55-65).

It would have been obvious to one of ordinary skill in the art to vary the thickness in the microplates of Donald B. rising or Coasssin et al as taught by Mathus et al to allow UV radiation to pass through the bottom of the wells as to obtain the desired wavelength.

With respect to claim18, it would have been further obvious to one of ordinary skill in the art to vary temperature, hardness and flexibility in microplate assemblies because they are routine optimizations that are almost always determined in material fabrication. Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been obvious for one of ordinary skill in the art to employ these modifications as a means of optimizing the devices provided by the art.

7. Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donald B. Rising or Coasssin et al in view of Mohan et al (USP# 5,888,830).

The teachings of Donald B. Rising and Coasssin et al are set forth above and differ from the instant claims in not teaching such limitations as a lid that has a plurality of caps with inlet/outlet ports, a temperature control element and a vacuum fixture.

However, Mohan et al teaches a capping plate with a plurality of caps that corresponds to an array area and seals the reaction vessel. Each cap has access to an inlet and outlet port and the microplate assembly has a temperature control element

(See Figure 1 and 1A). The microplate assemble has a vacuum fixture on the surface of the interior chamber (See Figure 1). A cleavage section that has a chamber containing a plurality of vial ports, each holding separate vials with inlet and outlet ports for connecting the chamber to a vacuum supply (col. 2, lines 55-65). The temperature control element can be used to heat or cool fluid that circulates through channels in the plate (col. 13, lines 1-7). The microplate assembly also provides for a silicon heating pad that is sandwiched between the top heater block and the bottom heater block and is connected by leads to a heater control (See Figure 1) which maintains the desired heat level (col. 12, lines 59-63). Such a system would provide an improved apparatus for performing multiple chemical reaction on a solid support in a parallel fashion in a simple and easy manner (col. 1, lines 52-64).

It would have been obvious to one of ordinary skill in the art to incorporate the capping plate of Mohan et al into the microplate of Donald B. Rising or Coasson et al to seal the reaction vessel. The vacuum fixture taught by Mohan et al is also obvious for connecting the chamber to a vacuum supply to assist in the flow of fluid. It would have been further obvious to incorporate a heater control element to maintain a desired heat level since such a heating element is usually required for chemical reactions. One of ordinary skill in the art would have also been motivated to add the additional features taught by Mohan et al into the microplate assembly of Donald B. Rising or Coasson et al in order to provide an improved apparatus for performing multiple chemical reactions on a solid support in a parallel fashion in a simple and easy manner.

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8. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donald B. Rising or Coassin et al in view of Mohan et al and in further view of Stylli et al (USP#5,985,214).

The teachings of Donald B. Rising and Coassin et al are set forth above and differ from the instant claims in failing to teach a peristaltic pump.

However, Stylli et al teaches in his present invention systems and methods that utilize automated and integratable workstations for identifying chemicals having useful activity (See abstract). When live cells are being dispensed, it may be necessary to provide re-circulation of the cell culture through a fluid system in order to prevent adhesion or pooling of the cells, which can be accomplished by a peristaltic pump (col. 59, lines 20-32).

It would have been obvious to one of ordinary skill in the art to include a peristaltic pump in the microplate of Donald B. Rising or Coassin et al that is part of the microplate assembly of Mohan et al of claim 22 to provide re-circulation of the cell culture that would prevent adhesion or pooling of the cells.

Remarks

Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Bengt La Motte (USP# 5,882,595) disclose and automatic processing system for use in a solid phase biospecific binding and DNA sequencing techniques.

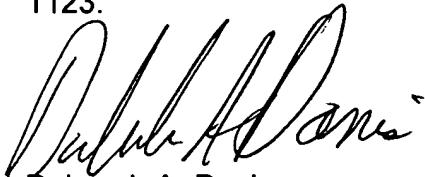
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B. Arthur Schleifer et al (USP# 6,309,828) disclose a method and apparatus for fabricating replicate arrays of nucleic acid molecules.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.



Deborah A. Davis
CM!-8D08
July 29, 2002



LONG V. LE
SUPERVISORY PATENT EXAMINER
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07/29/02